

~~10-144 DEPARTMENT OF HUMAN SERVICES~~~~BUREAU OF HEALTH~~~~Chapter 259: RULES ESTABLISHING BLIND SEROPREVALENCE SURVEYS
FOR OCCURRENCE OF HIV IN NEWBORNS~~

~~SUMMARY: These rules set forth the procedures to be followed by the Bureau of Health,, the Public Health Laboratory or other laboratories with which the bureau of Health enters into an agreement for the purpose of screening blood specimens from newborn Infants for the presence of HIV Infection. This seroprevalence survey is conducted solely for purposes of targeting future public health efforts to control HIV infection. These rules are designed to ensure anonymity of test subjects.~~

~~1.0—PURPOSE~~

~~These rules implement section 19203(5) of Title 5 of the Maine Revised Statutes Annotated with respect to blind seroprevalence, surveys of newborn infants and are promulgated pursuant to 22 M.R.S.A. §§3, 42, and 1012.~~

~~2.0—DEFINITIONS~~

~~2.1—Antibody to HIV. "Antibody to HIV" means the specific Immunoglobulin produced by the body's Immune system in response to HIV.~~

~~2.2—Bureau. "Bureau" means the Bureau of Health, Department of Human Services.~~

~~2.3—Commissioner. "Commissioner" means the Commissioner of the State of Maine Department of Human Services.~~

~~2.4—HIV. "HIV" means the human immunodeficiency virus, Identified & a the causative agent of Acquired Immune Deficiency Syndrome, or AIDS.~~

~~2.5—HIV Infection. "HIV infection" means the state wherein HIV has Invaded the body and is being actively harbored by the body.~~

~~2.6—Seroprevalence. "Seroprevalence" means the rate of seropositivity within a given study sample.~~

~~2.7—Testing category. "Testing category" means a group of no fewer than two hospitals in a specific geographic area.~~

~~3.0—SEROPREVALENCE SURVEY~~

~~With the approval of the Commissioners, the Director of the Bureau of Health may initiate a seroprevalence survey to determine the rate, of HIV infection among all infants born in this State. This survey must meet all requirements of these rules and other applicable laws. Failure to follow the procedures set forth in these rules may subject persons conducting the seroprevalence survey to the penalties provided in 5 M.R.S.A. §19206, as amended.~~

~~NOTE: The incidence of HIV seropositivity among infants represents an indicator of maternal rates of HIV infection. Maternal HIV antibody status can be determined from the newborn specimen because maternal IgG antibodies readily cross the Placenta and are present in the neonate's blood at approximately the same concentration as in the mother.~~

~~4.0—PROCEDURES~~

~~Under 5 M.R.S.A. §19203(5), the Department of Human Services says, for the purpose of research and without first obtaining Informed consent to the testing,, subject body fluids to a test for the presence of an antibody to HIV, if the testing is performed in a manner by which the identity of the test subject or his parents is not known and say not be retrieved. Any seroprevalence surveys of newborn infants must be conducted in accordance with the following procedures:~~

~~4.1—When the Commissioner determines, based on established principles of public health, that there is a need for epidemiological data on the incidence of HIV infection among women of child-bearing age, the Bureau of Health say Initiate a seroprevalence survey of newborn infants* HIV tests on the blood of newborn infants will indicate the infection status of the mother and not necessarily that of the infant.~~

~~4.2—Upon approval by the Commissioner, the Director of the Bureau of Health may enter into a written agreement with the Director of the Public Health Laboratory or the Director of a public health laboratory of comparable quality in another state, depending upon where the testing will take place. no survey may be undertaken without first obtaining a written agreement which contains the following standards, which standards shall govern the blinded newborn screening program:~~

~~(a)—the public health laboratory selected must be specially trained and equipped to handle the paper-absorbed newborn specimens described in subsection Me and must have demonstrated proficiency with HIV testing and capabilities for large capacity testing of newborn specimens.~~

- ~~(b) — The agreement shall clearly identify the population group under study, which population group must be large enough to ensure anonymity. For purposes of a newborn seroprevalence survey, the population group under study say be defined as all infants born in this state whose blood samples are submitted to the Public Health Laboratory for metabolic screening pursuant to 22 M.R.S.A. §1532.~~
- ~~(c) — The identification of the population group under study shall not include or result in the identification of individual test subjects.~~
- ~~(d) — The seroprevalence survey shall be based solely on blood samples submitted to the Public Health Laboratory for tooting pursuant to 22 M.R.S.A. §1532. The actual testing of the samples may take place either at the Maine Public Health Laboratory or at a public health laboratory in another State which has received the blood samples from the Maine Public Health Laboratory and has entered into a written agreement with the Director of the Bureau of Health pursuant to these rules.~~
- ~~(e) — Blood samples may not be tested for the presence of HIV until after they have undergone all other tests for which they were sent to the Public Health Laboratory or a comparable facility.~~
- ~~(f) — Upon completion of all other tests such as metabolic screening, the blood specimen shall be tendered anonymous by removing a disk of dried blood from the collection paper containing personally Identifying information. Blood specimens so removed shall not contain any personally Identifying information other than the month and year in which the blood specimen was obtained.~~
- ~~(g) — Following removal of the blood specimen from the collection papers the blood specimen shall be placed into, a container with specimens from other sampled hospitals in the same testing category.~~
- ~~(h) — After the specimens have been placed in a container with other specimens from the appropriate testing category, no HIV tests shall be performed until at least 200 specimens have been placed in the container for that testing category.~~
- ~~(i) — The person removing the blood specimens from the collection paper shall not be the same person to perform the HIV testing on those specimens.~~

- ~~(j) — The testing of the specimens for the HIV antibody shall not take place in the same room where those specimens were removed from collection papers.~~
- ~~k — The testing procedure shall utilize a licensed Enzyme-Linked Immunosorbent Assay (ELISA) screening kit for testing antibodies to HIV and a published Western Blot procedure suitable for testing filter paper specimens.~~
- ~~(l) — After the blinding procedure set forth above has been completed and the specimens have been tested for the HIV antibody. The results of those tests shall be released to the Director of the Bureau of Health at least once every three months by testing category, and the specimens shall be destroyed.~~

~~5.0 — PENALTIES~~

~~Failure to comply with the standards set forth in these rules may result in the imposition of such civil penalties as specified under 5 M.R.S.A. §19206 as well as 22 M.R.S.A. §47.~~

~~STATUTORY AUTHORITY: — 22 M.R.S.A. §3, 42, 1012 (l) (B) (C)
5 M.R.S.A. §19203 (5).~~

~~EFFECTIVE DATE: July 2, 1988~~

~~EFFECTIVE DATE (ELECTRONIC CONVERSION): May 5, 1996~~